

Patient Safety Alert

Veterans Health Administration Warning System Published by VA Central Office

AL06-04

November 1, 2005

- Item:** Heat maintainers for Stellant CT Injector Systems, manufactured by MEDRAD, Inc. Part numbers for the heat maintainers are 3007871, 3007872, 3009707 and 3009708. (Note: Part numbers for the Stellant injector systems are 3007301, 3010432, 3007300 and 3010091.)
- Specific Incident:** The manufacturer reports the heat maintainers used on the Stellant injector systems may malfunction and overheat the syringe and contrast media. No patient or technologist injuries have been reported thus far. MEDRAD has identified 42 VA Medical Centers with the affected heat maintainers.
- Action:** If you did not receive and reply to MEDRAD's October 12 letter (attached) determine if you have the affected heat maintainer.
If you have a Stellant injector system;
1. Disconnect the heat maintainer from the Stellant system.
 2. Complete the reply form (located in the attached letter) and fax the form to MEDRAD at 412-406-0941.
 3. If you must use the heat maintainer before a field correction kit can be provided by Medrad, take the following actions:
 - a. Request warning stickers from MEDRAD and attach them to the heat maintainers.
 - b. Inform CT technologists of the risks and have them:
 - o Minimize the time of heat maintainer/syringe contact
 - o Check for abnormally hot syringes just before injection
 - o Observe syringe characteristics. IMMEDIATELY discontinue use of any syringes that deform or turn white, and contact MEDRAD at 1-800-633-7231 x3729
- Addl Information:** Do not dispose of the heat maintainer, MEDRAD, will be providing a field correction kit in January 2006.
Also, please contact the VA Center for Engineering Occupational Safety and Health (CEOSH) if you are affected and did not receive MEDRAD's letter so we can work with MEDRAD to update their records.
- Source:** CEOSH, Manufacturer and FDA
- Contact:** MEDRAD (for stickers) - Tony Maiore at 412-767-2400, ext. 3350
CEOSH - Paul Sherman, at (314) 543-6700

URGENT MEDICAL DEVICE FIELD CORRECTION

October 12, 2005

**RE: MEDRAD Stellant CT Injector Systems (Part Numbers:
3007301, 3010432, 3007300, and 3010091) – Heat Maintainer
Users**



MEDRAD, Inc.
One Medrad Drive
Indianola, PA
15051-0780
U.S.A.
(412) 767-2400
www.medrad.com

Dear Valued Customer,

It has been determined that the heat maintainers used on the Stellant injection systems (see Attachment 1) may malfunction and overheat the syringe and contrast media. This could potentially result in patient or technologist injury.

Please note that we have had no reports of patient injuries resulting from the use of these heat maintainers, but are initiating this action as a precautionary measure.

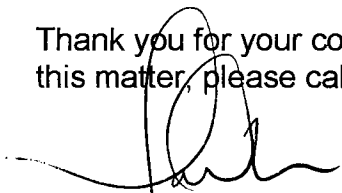
We are requesting that you do the following:

1. Verify that you currently have a Stellant heat maintainer at your institution with one of the following part numbers - 3007871, 3007872, 3009707, 3009708 (see Attachment 1 for location of the part number on the heat maintainer).
2. Attach the included warning label to the heat maintainer as shown in Attachment 2 and assure that all CT technologists that use the Stellant system understand the associated warnings.
3. Disconnect the heat maintainer from the Stellant system.
4. Do not dispose of your heat maintainer. A free field correction kit that will attach to the existing heat maintainer will be provided to you in January 2006.
5. If it is necessary to use the heat maintainer to complete a clinical procedure, it is critical that the following precautionary steps be followed:
 - Minimize the time between attachment of the heat maintainer to the loaded syringe and injection AND check for an abnormally hot syringe just prior to injection.
 - If the syringe deforms or turns white, discontinue use of the heat maintainer immediately and call MEDRAD at 1-800-633-7231, ext. 3729.
6. Complete the attached form and fax it back to MEDRAD at 412-406-0941.

7. **Please complete and fax this form even if you do not have the referenced product so that we can maintain proper accountability for all heat maintainers shipped.**

We apologize for any inconvenience that this is causing. For your information, this field correction is also being reported to the US Food and Drug Administration and other regional authorities, as required.

Thank you for your cooperation. If you have any questions concerning this matter, please call 1-800-845-2533.

A handwritten signature in black ink, appearing to read 'Julio Rivera', with a stylized flourish extending to the left.

Sincerely

Julio Rivera, Sr. Vice President, Corporate Compliance

Attachment 1

Stellant Heat Maintainer



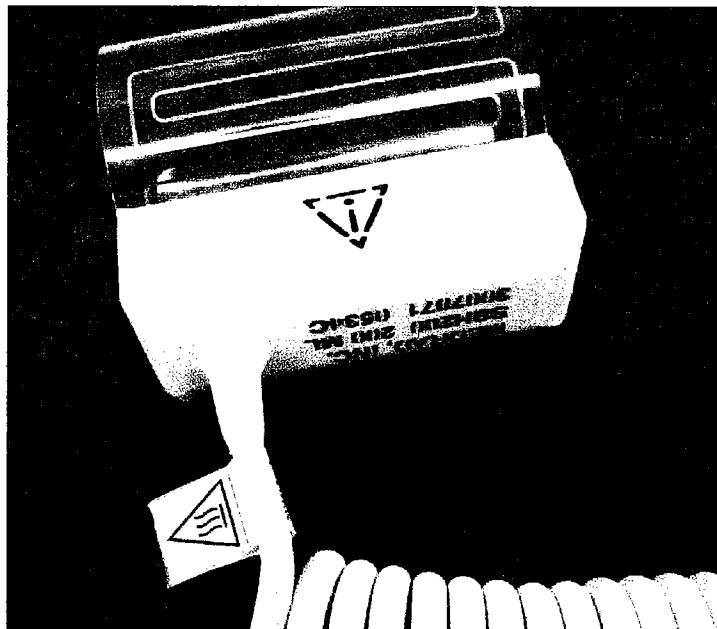
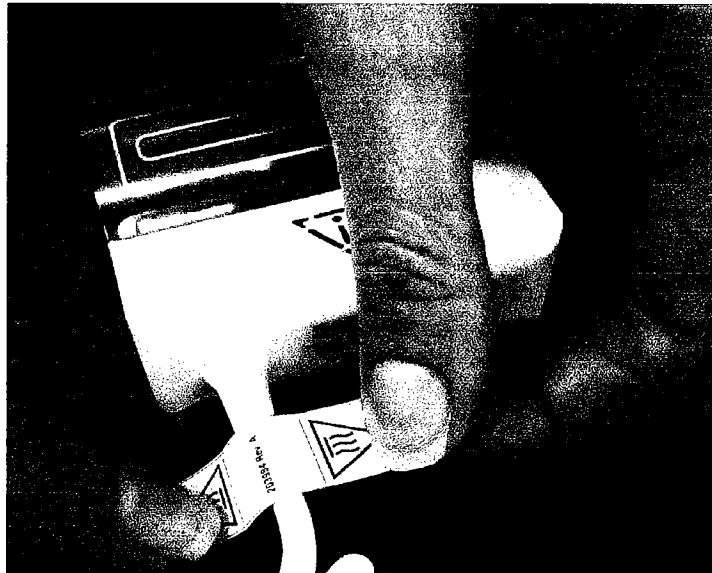
Heat Maintainer Part Number Location



Attachment 2 Warning Label Placement



WARNING: The heat maintainer may overheat resulting in patient or operator injury; **DISCONTINUE USE.** If necessary to complete a clinical procedure, minimize the time between attachment of the heat maintainer to the syringe and the time of injection AND check for an abnormally hot syringe just prior to injection.



October 12, 2005

URGENT FIELD CORRECTION

FROM:

APPLY ADDRESS LABEL HERE

FAX TO: Quality System Compliance

412-406-0941

RE: MEDRAD STELLANT HEAT MAINTAINERS

I have checked inventory at my institution and have verified the following:

___ I have none of the referenced systems at my institution.

___ I have confirmed that I have an impacted system(s) and have completed the steps outlined in the letter.

___ Quantity of heat maintainers at my institution

Signature

Date

Name (Please Print)

Title (Please Print)

Phone #

PLEASE COMPLETE THIS FORM, EVEN IF YOU HAVE NO INVENTORY ON-HAND. SIGN, DATE & FAX TO MEDRAD QUALITY SYSTEM COMPLIANCE AT 412-406-0941. THANK YOU!!!